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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,008	07/14/2003	Patricia J. Andolino Brandt	53867US018	6035

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EXAMINER

GEORGE, KONATA M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/619,008	ANDOLINO BRANDT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Konata M. George	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15 and 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>October 17, 2003</u> .  | 6) <input type="checkbox"/> Other: ____.                                    |

### **DETAILED ACTION**

Claims 1-19 are pending in this application.

#### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on October 17, 2003 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

#### ***Specification***

2. The specification contains an attorney docket number on page 10, line 20. Applicant is required to provide the corresponding Serial No., including date of application.

#### ***Restriction Requirement***

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-13, 15 and 17-19, drawn to a fluid composition, classified in class 424, subclass 70.1.
  - II. Claim 14, drawn to a transdermal drug delivery system, classified in class 424, subclass 449.
  - III. Claim 16, drawn to a covering device, classified in class 604, subclass 41.

The inventions are distinct, each from the other because:

Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Group I is distinct from Group II because Group I invention requires a composition for hair care unrelated to the transdermal drug delivery system of Group II.

Group II is distinct from Group III because Group II is drawn to a patentable distinct article capable of supporting a separate patent within the art. The art does not recognize the equivalency between Group II drug delivery system and a Group III bandage for covering wounds.

Group I is distinct from Group III because the composition of Group I is not required to be present in the Group III bandage.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Cheree Haswell on April 14, 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-13, 15 and 17-19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14 and 16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1 and 6-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,627,216 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patent and the application are directed towards a fluid composition comprising an effective amount of a tacky component, a film-forming, non-tacky component and a volatile solvent. The difference between the patent and the instant application is that in claims 1 and 2 of the patent the

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film forming component is defined as comprising a siloxane-containing polymer and in the instant application it is at least one low surface energy, surface seeking moiety. In the instant application, claims 6-8 disclose examples of the film-forming component one of which can be a siloxane-containing polymer.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13, 15 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-19 discloses using a fluid composition as a covering element onto a surface. It is unclear by way of the claims what the "surface" is. Please define what the surface is in the claims.

6. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the examiner how water alone is a volatile solvent. Please clarify.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-4, 6, 7, 9-13, 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salamone et al. (USP 5,103,812).

Salamone discloses a conformable bandage and coating material that is applied to the skin as a liquid and dries to form a solid protective film (col. 1, lines 15-17 and col. 2, lines 8-13). The fluid composition comprises siloxane-containing polymers, together with additional polymerizable monomers incorporated into a solvent system (col. 3, line 10-col. 6, line 25). Column 3, lines 27-49 teach that the addition monomers can be methyl acrylates and derivatives thereof. It is taught that the monomers can be in concentrations of 0-85% mole of the polymer (col. 3, lines 63-65). Column 5, lines 50-54 and column 6, lines 16-25 teach the solvent system as volatile liquids silicones (i.e. polydimethylsiloxane) or polar liquids or solvents (i.e. ethanol, isopropanol, etc.) Column 7, lines 30-42 teach that medicaments may be incorporated into the liquid. The prior art does not teach the non-tacky component comprising at least one low surface energy, surface seeking moiety.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a siloxane-containing polymer as the non-tacky component, because the patent teaches that the siloxane-containing polymers of a controlled weight provides non-tacky characteristics (col. 4, lines 30-37). As stated above in column 3, line 10-col. 6, line 25 is taught that the composition comprises these elements. Applicant in claims 7 and 8 also disclose the use of siloxane-containing

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polymer as non-tacky components. The expected result would be a liquid composition the dries upon application to the skin that has non-tacky characteristics.

### ***Conclusion***

8. Claims 1-13, 15 and 17-19 are rejected.

### ***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (571) 272-0602. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Konata M. George  
Patent Examiner  
Art Unit 1616